

DOCKET NO: 280271US0X PCT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: :  
HIROSHI MIURA, ET AL. : EXAMINER: PALENIK, JEFFREY T.  
SERIAL NO.: 10/554,921 :  
FILED: OCTOBER 31, 2005 : GROUP ART UNIT: 1615  
FOR: COMPOSITION CONTAINING :  
MEDICINE EXTREMELY SLIGHTLY  
SOLUBLE IN WATER BEING  
EXCELLENT IN ELUTING PROPERTY  
AND METHOD FOR PREPARATION  
THEREOF

DECLARATION

COMMISSIONER FOR PATENTS  
ALEXANDRIA, VIRGINIA 22313

SIR:

I, Tsutomu KAJINO, hereby declare:

1. In 1988, I received a Master of Agriculture degree from Nagoya University, in the field of biotechnology. In 2000, I received a Doctor of Agriculture degree from Nagoya University. My studies were directed to the subject of "Quality control of recombinant proteins".

2. I have been employed by KABUSHIKI KAISHA TOYOTA CHUO KENKYUSHO from 1988 to the present.

3. From 1988 to 2002, I worked as a researcher for Biotechnology Division at KABUSHIKI KAISHA TOYOTA CHUO KENKYUSHO in the area of application of biomolecules.

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4. From 2002 to the present, I have been the program manager of the Frontier Research Center at KABUSHIKI KAISHA TOYOTA CHUO KENKYUSHO. My duties as the program manager of the Frontier Research Center include responsibility for the management of research and development projects.

5. I am a named inventor in the above-captioned patent application, of which KOWA CO., LTD., and KABUSHIKI KAISHA TOYOTA CHUO KENKYUSHO are the assignees. I am also familiar with and have worked with the products and methods described in the above-captioned patent application.

6. I have been informed that the Examiner in the above-captioned patent application has requested information regarding the properties, structure, etc., of the silicas described in the specification of the above-captioned patent application at page 9, lines 2 to 7, and designated "FSM," which are products of Toyota Central R&D Labs. Inc.

7. I have obtained information regarding the above-referenced products in response to this request. I obtained this information by carrying out experimentation to evaluate the above-referenced products. The information includes the average pore diameter, the specific surface area, and the total pore volume of pores having diameters within  $\pm 40\%$  of the average pore diameter for each of the above-referenced products, which are shown in the Table attached hereto. The information further includes X-ray diffraction patterns for each of the above-referenced products, which are shown in the Figures attached hereto.

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8. All statements made herein of my own knowledge are true, and all statements made on information and belief are believed to be true; these statements were made with the knowledge that willful false statements are punishable by fine and/or imprisonment under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of this application or any patent issuing therefrom.

Date: 14. Jan. 2010.

Tsutomu Kajino  
Tsutomu KAJINO

Attachments:  
Table  
Figures